Draft Deliberative – Do Not Distribute September 2, 2016

**EAM Roll-Out Questions on GE Insects** 

Why would EPA now regulate a GE mosquito used for population control?

## Ex. 5 Deliberative Process (DP)

Why is the question of which agency will regulate GE mosquitoes being addressed at this time as part of the Coordinated Framework Update effort? Why not when companies first indicated they were developing GE mosquitoes?

# Ex. 5 Deliberative Process (DP)

What does this mean for the developer of a GE mosquito, Oxitec, whose product is currently under review at FDA?

## Ex. 5 Deliberative Process (DP)

How does EPA regulate GE pesticides?

# Ex. 5 Deliberative Process (DP)

Does USDA play a role in the regulation of GE insects?

## Ex. 5 Deliberative Process (DP)

Will the Key Haven vote in November 2016 on the town's sentiment on testing of the Oxitec mosquito affect the regulation of GE mosquitoes?

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#### Ex. 5 Deliberative Process (DP)

Are there other modern biotechnology mosquito products that are close to the market at this time?

#### Ex. 5 Deliberative Process (DP)

How does the mosquito being regulated by EPA differ from the mosquito being regulated by FDA?

# Ex. 5 Deliberative Process (DP)

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How did it happen that one mosquito product intended to lower the number of mosquitoes in the environment is currently being reviewed by the EPA as a pesticide, while another mosquito product which is also intended to lower the mosquito population, is being reviewed by FDA?

#### Ex. 5 Deliberative Process (DP)

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What actions has EPA taken to date on the Wolbachia mosquito product?

# Ex. 5 Deliberative Process (DP)

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# Ex. 5 Deliberative Process (DP)

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What kind of information does EPA consider when evaluating Wolbachia in mosquitoes?

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#### Ex. 5 Deliberative Process (DP)

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Will the mosquito population control product based on the Wolbachia microorganism continue to be regulated by EPA?

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When is EPA likely to make a regulatory decision on the Wolbachia product?

#### Ex. 5 Deliberative Process (DP)

Will my children be safe?

Ex. 5 Deliberative Process (DP)

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Commented [WC1]: We don't really answer the question here on timing. Can we venture to say 'in the coming months' or some such thing? And maybe point out there is more than one product in the pipeline?

#### Ex. 5 Deliberative Process (DP)

**Commented [WC2]:** I wonder if copepod is too technical depending on the audience. General public?

Why do we need a GE mosquito when chemical pesticides can be used to kill mosquitoes?

#### Ex. 5 Deliberative Process (DP)

Commented [WC3]: Do we want to go there considering it could implicate some of our colleagues and the products they register? What if we said that chemical pesticides are often more broad spectrum in their action and can be environmentally persistent, as compared to this biological approach?

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